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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DAVIS, BRIAN J	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
08/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,240	KOHNO ET AL.	
	Examiner	Art Unit	
	Brian J. Davis	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Applicant's election, without traverse, of the species of example 184 (specification page 116) as the species elected to begin prosecution is acknowledged. The election/restriction is hereby made FINAL.

Specification

The disclosure is objected to because of the following informalities: the parentage of the application should be included in the specification immediately after the title. Appropriate correction is required.

Claim Rejections - 35 USC § 112, FIRST PARAGRAPH

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating or ameliorating (the symptoms of) autoimmune diseases, rheumatoid arthritis, etc., does not reasonably provide enablement for the prophylaxis or prevention of such diseases. (One of the definitions of *prophylaxis* is prevention.) The specification does not enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

With regard to rejections under 35 USC 112, first paragraph, the following factors are considered (*In re Wands* 8 USPQ 2d 1400, 1404 (CAFC 1988)): a) Breadth of claims; b) Nature of invention; c) State of the prior art; d) Level of ordinary skill in the art; e) Level of predictability in the art; f) Amount of direction and guidance provided by the inventor; g) Working examples and; h) Level of experimentation needed to make or use the invention based on the content of the disclosure.

a) The claims are quite broad: "The immunosuppressive agent...for use as a prophylactic or therapeutic agent for autoimmune diseases." (claim 12; claims 13-16 expand the list of diseases). "A method of preventing or treating autoimmune diseases, rheumatoid arthritis, [etc.]." (claim 17).

b,c) The nature of the invention is determined in part by the state of the prior art.

Even a cursory perusal of the teachings of the medicinal arts reveals that they have not advanced to the point where complex conditions such as autoimmune diseases can be said to be preventable. The art, in general, teaches, instead, that what can be prevented with regard to such disorders are their associated symptoms.

d) The level of skill in the art is considered to be relatively high.

e) The level of predictability in the art is considered to be relatively low.

The basis of all modern medicine and biology is, of course, chemistry. Yet even under the best of circumstances, and several hundred years after Lavoisier laid the foundations of its modern practice, chemistry remains an experimental science. Neither

the medicinal/biological arts nor the chemical arts upon which they are based have advanced to the point where certainty has replaced the need for clinical and/or laboratory experimentation.

f,g) The amount of direction provided by the inventor is considered to be determined by the specification and the working examples. Applicant's data do not demonstrate that the instant compounds prevent autoimmune diseases, rheumatoid arthritis, etc.

h) Regardless of the amount of experimentation involved, applicant's claims to the prevention the above diseases is simply not believable given their present understanding in the contemporary medicinal arts. It is settled case law that allegations of utility that are not believable in light of the contemporary knowledge in the art must be substantiated by acceptable evidence or stricken from the specification. In re Ferns, 163 USPQ 609 (CCPA 1969; Ex Parte Moore, 128, USPQ 8 (BPAI 1960); In re Hozumi, 226, USPQ 353 (Comr. Dec. 1985); MPEP 706.03(n) and 706.03(z).

Allowable Subject Matter

The elected species has been searched and is deemed free of the prior art. The search was therefore expanded as called for under current Office Markush examination practice, a compound-by-compound search, to include a single additional compound. That compound is defined when: R_1=halogen=F; R_2=R_3=R_4=R_5=R_6=R_7=H; X=O; and n=1. A rejection follows.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17, in so far as they read on the species cited above, are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 2000001388 (CAPLUS abstract). The examiner notes for clarity of the record that this is the WIPO equivalent of EP 1092435 cited by applicant in the IDS. The reference teaches applicant's compound (last compound on page 52).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached at 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BRIAN DAVIS
PRIMARY EXAMINER

Brian J. Davis
August 18, 2007